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David W. Highet, VP & Chief IP Counsel			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,030

Applicant(s)

HOWELL, GLADE H.

Examiner

QUYNH-NHU H. VU

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Amendment filed on 2/4/08 has been entered.

Claims 1-20 are present for examination.

Applicant's arguments filed on 2/4/08 have been fully considered but are not persuasive.

Therefore, claims 1-20 are rejected in the new ground rejections as set forth in the office action mailed 8/1/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 1, 8 and 13, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 5,676,656) in view of Brimhall (US 5,385,554).

Brimhall '656 discloses a septum and needle assembly comprising: a needle 40 having a proximal end and a distal end; a housing; and septum (Fig. 2) disposed in the housing; wherein the needle is sliding disposed within the septum. A slit is disposed within the septum and the needle is sliding disposed within the slit (claim 2). A tube 50 attached to and in fluid communication with the housing (claim

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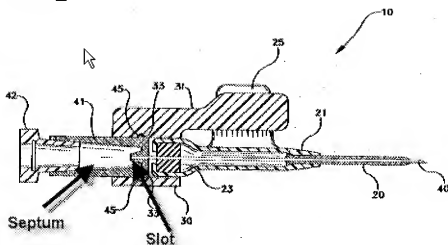
3); a female adapter 51 attached to the tube (claim 4). Brimhall '656 does not disclose the needle defines a notch adjacent to the distal end.

Brimhall '554 discloses that a needle 16 having a notch 19 located adjacent to the distal end. Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Brimhall '656 with an opening (notch like opening 19), as taught by Brimhall '554 in order to permit fluid to flow from lumen into annular space.

Regarding to limitation "a septum disposed in the housing and having a length greater than the notch distance". It is noted that it would have been an obvious matter of design choice to the septum having greater length than the notch distance, since applicant has not disclosed that limitation above solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the prior art.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. "such that leakage of bodily fluid emanating from the distal end of the needle and the notch is contained within the septum even when the needle is slidably disposed within the septum", a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

FIG-2



Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 5,676,656) in view of Brimhall (US 5,385,554) and further in view of Schaffer (US 5,429,616).

Brimhall '656 in view of Brimhall '554, disclose all claimed subject matter except for biasing element engaged to the septum; wherein the septum has a dumbbell shape and the C-shaped clip is directly engaged to the septum.

Schaffer discloses a biasing element 44, 46, 70; wherein the biasing element is a C-shaped clip (Figs. 3-6); a septum (include 50, 26 and 28); and the C-shaped clip is directed engaged to the septum.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Brimhall '656 in view of Brimhall '55a with the septum and the biasing element, as taught by Schaffer, for the benefits of gripping and pushing toward each other to compress the sealing material and occlude the apparatus.

Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffer (US 5,429,616) in view of Brimhall (US 5,385,554).

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Schaffer discloses a catheter apparatus for insertion into a blood vessel including: a catheter 40; a housing in fluid connection with the catheter; a septum (includes 32, 50, 26, 28); a needle 14 sliding disposed with respect to the catheter, the needle 14 having a proximal end and a distal end; a finger grip 44, 46 attached to the needle at its proximal end; the septum includes an elastic plug 28 having a proximal end 32 and a distal end 34, an outside longitudinal surface 26, 50 extending between the proximal end and the distal end, and a slit 52 (claims 9-13); a biasing element (Figs. 3-6); the elastic plug comprises an annular groove; the biasing element is a C-shaped clip; the electrometric plug has a dumbbell shape (claim 18); wherein the biasing element is a C shaped clip that does not extend completely about the circumference of the elastic plug (claim 20).

Schaffer does not disclose a needle having a notch and a distal end of opening in the distal end of the needle.

Brimhall '554 discloses that a needle 16 having a notch 19 located adjacent to the distal end. Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Schaffer with an opening (notch like opening 19), as taught by Brimhall '554 in order to permit fluid to flow from lumen into annular space.

Regarding to limitation "a septum disposed in the housing and having a length greater than the notch distance". It is noted that it would have been an obvious matter of design choice to the septum having greater length than the notch distance, since applicant has not disclosed that limitation above solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the prior art.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. "such that leakage of bodily fluid emanating from the distal end of the needle, catheter and the notch is contained within the septum even when the needle is slidably disposed within the septum", a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

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Regarding claims 19-20, it is well known in the art to provide a tube attached to the proximal end of the catheter, as applicant admitted in para [0005].

Response to Arguments

Applicant argues that the cited art does not teach nor suggest a design that combines a notched needle with a septum or elastic plug that operates in a manner such that leaks are automatically and consistently controlled.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner

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